REMARKS

Claims 19, 21 to 27, 29 to 48 are in the application. Claims 20 and 28 have been cancelled. Claims 35 to 48 have been added. Support for the newly added claims lie in the original claims as filed. No new matter is believed added.

Rejection under 35 USC §112, first paragraph

Claims 19 to 34 are rejected under 35 USC §112, first paragraph as failing to comply with the written description requirement. The basis for this rejection is "that one of skill in the art cannot use the specification to make or use the claimed invention without undue experimentation." Applicants respectfully traverse this rejection.

Applicants argue that to actually make and use the invention herein is actually quite simple and described in more than sufficient detail to enable a skilled artisan to practice the invention. The Examiners rejection under this paragraph is apparently based upon the "lack of support in the specification for the intended use", be it of prevention of colon cancer or prevention of breast cancer.

The Examiner has also maintained that the Baron article teaches that animal models do not correlate with human epidemiological data. Applicants continue to traverse the use of Baron for the purposes of establishing non-enablement of the specification. However, even so, the Examiner's reading of Baron is incorrect.

Dr. Baron's article does not debunk the use of animal models in this area. He indicates at most that they have shown differing results [col. 2, 1rst paragraph , page 2904]. Those results being predicated upon a lack of standardized usage on the term "dietary fiber" [col. 2, 2nd paragraph , page 2904]. Baron goes on to discuss the use of characterization of fiber by food group, or by the solubility of the fiber, e.g. soluble or insoluble. The problem lying in the many studies in that no one really knows what was actually measured for each of the various fibers. Baron states in the 1rst full paragraph, column 1, page 2905 that "In animal models, insoluble fibers such as wheat fiber have typically

resulted in inhibition of bowel carcinogenesis, but soluble fibers such as pectins have tended to increase the number of tumors".

In Column 2, 1rst and 2nd full paragraphs, p. 2905, Baron describes a study which appears in the same journal, that by Park et al. In fact the findings of Park et al. suggest that in human, fiber did confer prevention for an increased risk for those who were "fiber deficient". He also suggests that fiber intake at the "high end" may confer a modest decrease in risk.

Baron also discusses an EPIC cohort analysis which provides for a much higher reduction in risk of colorectal cancer in individuals than those reported in Park et al. discussed above. Consequently, contrary to the Examiners point that Baron refutes an animal model (which is doesn't) the discussion of human models directly correlates with Applicants finding in the models described herein. Therefore, rather than negate a finding of non-enablement, it but reinforces Applicants invention as claimed herein.

It should be expressly noted that Applicants claims require a water soluble, non-fermentable cellulose derivative which is methylcellulose, alone or in combination with an insoluble fiber which is wheat bran. This is different from the soluble fiber fruit and vegetables and cereal fibers as discussed in Baron.

A lack of consensus is not a suitable ground for rejection. Applicants have presented clear evidence using the claimed material herein, methylcellulose. All 3 combinations of administration (with methylcellulose) yielded fewer aberrant crypt foci in the Examples herein. Consequently, Applicants have indeed provided sufficient nexus to the claimed invention herein. There is no undue burden on the part of the skilled artisan to make and use Applicants claimed invention. Applicants have used an art recognized model and provided data in such model. Therefore, reconsideration and withdrawal of the rejection to the claims for lack of enablement is respectfully requested.

Rejection under 35 USC §103

Claims 19 to 34 are rejected under 35 USC 103(a) as being unpatentable over Ohno et al., US 4,017,598) in view of Alva-Amco, Fibre Natural, 1996. Applicants respectfully traverse this rejection.

Ohno et al. discloses an oral tablet dosage form containing methylcellulose. The Fibre Natural ad also appears to be a description of an oral tablet containing a mixture of dietary fibers from different sources, including the addition of methylcellulose.

The Examiner's rejection is based upon that it "would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the Ohno methylcellulose preparations in a method of administration to a human, because Ohno clearly teaches that the methylcellulose preparations are intended for human consumption."

The Examiner further states that the:

> [The] "claims and the prior art cited have the same active steps and the same population of people (healthy human beings) is being treated…. Therefore, it appears that the intended use of the claimed methods does not alter the active method steps, the population being treated or the product being used in the claimed methods."

The Examiner appears to be saying that administration of a methylcellulose containing product to a human being, regardless of the composition, regardless of the dosage, regardless of the regimen, and regardless of the reason for administration to the person is all that is important to be the "same active steps". This can not be true or the law would never provide for second medical uses, which it does.

However, to better clarify and claim the invention, Applicants have added two independent claims sets which expressly require the additional insoluble fiber, wheat bran, rather than leaving it as an optional ingredient as presently claimed in Claims 19 and 27.

Consequently, Claims 19 and 27 both administer to a human being a methylcellulose containing product, optionally containing an insoluble fiber, wheat bran. Newly added Claims 35 and 42 both expressly require methylcellulose along with the insoluble fiber, wheat bran. Neither the product described by Ohno et al., nor the Fibre Naturale product meets the claim limitations of Claims 35 and 42. Therefore, the "product" being used in the methods of Claims 35 and 42 is not the same as the product of the cited prior art.

Applicants Claims 19 and 27 are not limited to a particular dosage form. The method of administration can include alternative forms, such as methylcellulose powder, currently available as Citrucel Powder, if provided for in an amount effective to reduce the incidence of colorectal cancers in the human. Claims 21 and 24 clearly indicate that alternative dosage forms are acceptable. Similarly, Claims 35 and 42 are also not limited to a particular dosage form, be it tablet, capsule or powder.

Neither Ohno et al., nor the Fibre Naturale Advertisement suggest or teach the use of their methylcellulose containing product for the methods disclosed and claimed herein.

Applicants direct the Examiner's attention to a recent CAFC decision, Perricone v. Medicis Pharmaceutical Corporation, 432 F. 3d 1368 (Fed. Cir., 2005) (copy enclosed). In this case the Federal Circuit most recently addressed the issue of new versus old uses, holding that a patent that disclosed use of a particular composition and particular method, but not to treat skin sunburn, did not inherently anticipate a patent on the use of the same composition and method to treat that problem. The use of an old method for treatment of a new problem (skin sunburn) is patentably new. Id. at 1378-79.

As the Court discussed "when considering a prior art method, the anticipation doctrine examines the natural and inherent results in that method without regard to the full recognition of those benefits or characteristics within the art field at the time of the prior art disclosure". Id at 1379.

Looking at our present case, the method patents are directed to a "reduction of the incidence of colorectal cancer". This claim term, "reduction of the incidence" does not appear in the cited prior art. The issue is not whether the composition being used is taken to treat constipation would inherently "reduce the incidence" but whether the Ohno et al. or Fiber Naturale discloses this application of their product for this usage.

As noted above, neither Ohno et al. or Fiber Naturale discloses Applicants claimed utilities. The administration of the methylcellulose product of Ohno et al. or Fiber Naturale does not necessarily comprise the same composition as Applicants, nor is necessarily administered in the same dosage regimen, nor necessarily administered in the same amounts, nor necessarily administered to the same patient population. The

Examiner has not shown that administration of the Ohno nor Fiber Naturale product results in Applicants invention as the natural and inherent result of such administration. For example, the prior art treatment may be of limited duration, e.g. a one off usage; for a limited time frame, e.g. satiety treatment for weight reduction; and not necessarily a life-long regimen for reduction of the incidence of a disease.

The Court further quoted in Perricone that, "New uses of old products or processes are indeed patentable subject matter"… (principals of inherency do not prohibit a process patent for a new use of an old structure)." Id at 1379. Hence, Applicants point that second medical uses are deemed allowable subject matter under US Patent Law.

The Examiner is "assuming" what the prior art neither discloses nor renders inherent:

a) The art does not disclose administration of a methycellulose composition for reduction of the incidence of colorectal cancer in a human (claim 19).
b) The art does not disclose administration of a methycellulose composition for reduction of the incidence of breast cancer in a human (claim 27).
c) The art does not disclose administration of a composition containing both methycellulose and wheat bran for reduction of the incidence of colorectal cancer in a human (claim 35).
d) The art does not disclose administration of a composition containing both methycellulose and wheat bran for reduction of the incidence of breast cancer in a human (claim 42).

The Examiner is also making an assumption that "the same active steps and the same population of people (healthy human beings)" are being treated (Page 6, 2nd , Office Action) by administration of the Ohno et al. product, or the Fiber Naturale product.

The Examiner has not provided any basis to state that the same populations of people being treated for the methods enumerated above as a) to d) would be the same population who are being treated for "constipation" or "irregularity" (e.g., the Fiber Naturale advertisement). One can also argue with the assertion that populations of people who take methylcellulose compositions for constipation are in fact a "healthy human being population". If you have a condition for which administration of an active substance having a pharmacological effect is necessary are you in fact a "healthy human being"?

It should be noted that the Ohno et al. reference does not even mention use of their methylcellulose tablet composition for "constipation" or "irregularity". Column 1, lines 25 to 33 disclose the use as one which will give "the sensation of full-stomach". The prior art in Ohno et al. is stated as "failing to disintegrate in the stomach after administration" and consequently, failing to "give the feeling of a full stomach by disintegrating and swelling in the stomach". The tablets of Ohno et al. are directed to the unmet need for a satiety treatment. Ohno et al. is not concerned with reduction of the incidence of colorectal or breast cancer, either alone or taken together with an insoluble fiber, e.g. wheat bran.

The mechanism of action for methycellulose in satiety treatments, or for treatment of constipation can and do affect different areas of the intestinal tract. Colorectal cancer treatment is concerned with the colon, not the stomach, nor the upper intestinal tract. Breast cancer tissue is even farther removed from gastrointestinal tract tissue. Therefore, the "affected skin areas" as the description is used in the Perricone case and are not the same as those areas affected by the methods of Ohno et al. or the Fiber Naturale product.

In addition to the cited references fails to teach or suggest every limitation of the claims, for instance, Claims 1, 9, 38 and 45, which require the dosage form of the methylcellulose, alone or in combination to be in a capsule, a powder or suspension dosage form.

Applicants respectfully traverse these rejections because the Office has failed to make out a *prima facie* case of obviousness as stated by the Examiner (page 6, 1rst ¶, Office Action) as to the claimed methods of use herein.

Under 35 U.S.C. §103, the Office bears the initial burden of establishing a *prima facie* case of obviousness. MPEP § 2142 at 2100-128-129 (Rev. 2, May 2004); *In re Piasecki,* 745 F.2d 1468, 1472 (Fed. Cir. 1984). To make out a *prima facie* case, the PTO must satisfactorily show that:

(1) the cited reference or combination of references teaches or suggests every limitation of the claim;

(2) the references relied upon, coupled with the knowledge generally available in the art at the time of the invention, contains some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine references; and

(3) the proposed modification of the references has a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made.

MPEP § 2143 at 2100-129; *Karsten Mfg. v. Cleveland Gulf Co.*, 242 F.3d 1376, 1385 (Fed. Cir. 2001); *Amgen Inc. v. Chugai*, 927 F.2d 1200, 1209 (Fed. Cir. 1991); *In re Wilson*, 424 F.2d 1382, 1385 (C.C.P.A. 1970).

The prior art, alone or together fails to provide any motivation to direct the skilled artisan to utilize methylcellulose, alone or with an insoluble fiber for the reduction of the incidence of colorectal or breast cancer, as claimed herein.

Applicants note that the Examiner seems to suggest the need for a showing of unexpected results to obviate the obviousness rejection. Because there is no *prima facie* case of obviousness here in view of Ohno et al., taken with Fiber Naturale, Applicants do not bear the burden of making such a showing at this juncture. Having established that the Office has failed to set forth a *prima facie* case of obviousness, Applicants respectfully request the withdrawal of the § 103 rejections.

Rejection under 35 USC §103

Claims 19 to 34 are rejected under 35 USC 103(a) as being obvious over Daggy et al., US patent 6,350,469 ('469). Applicants respectfully traverse this rejection.

The '469 patent shares a common priority document with Application No. 10/123,569 cited below. While the applications also all share a common inventor, Applicants do not believe that it is proper to have both a double patenting rejection and a rejection under 35 USC §103 in the same Office Action over related applications.

The Daggy et al. '469 patent is directed to a dosage form containing methylcellulose which rapidly disintegrates. The Examiner comments that Daggy teaches "specific daily

dosages that are within the range of those claimed. (Page 8, lines 3 and 4, Office Action). While Daggy teaches administration of tablets containing from 75mg upwards to 1000mg, the reference is silent to the total daily dosing requirements as described and claimed in the present application, e.g. Claims 25, 26, 33, 34, 40, 41, 47 and 48.

Again, as with the cited prior art references above, the '469 patent does not describe nor disclose use of methylcellulose compositions for the reduction of the incidence of colorectal or breast cancer. Applicants same arguments apply to the '469 patent as they do to the Ohno et al. or the Fiber Naturale advertisement, e.g. same population, formulations differences, different utilities, no disclosure, etc.

In view of these remarks, reconsideration and withdrawal of the rejection to the claims under 35 USC §103 is respectfully requested.

Judicially Created Doctrine of Double Patenting

Claims 19 to 34 are also provisionally rejected on the ground of nonstatutory obviousness type double patenting as being unpatentable over claims 38 and 40 of copending Application No. 10/123,569. Applicants respectfully traverse this rejection.

Application No. 10/123,569 has now granted as US Patent 7,132,114 ('114). The '114 patent is a divisional application of USSN 09/485,625, now US 6,372,253 ('253), and related to USSN 10/993,547, now US Patent 7,125,562 ('562). These three patents contain claims directed to a pharmaceutical composition and/or to a process of making that pharmaceutical composition. In contrast the present claims herein are directed to a particular method of treatment, not to a pharmaceutical composition, nor to a method of making that composition.

While Applicants do not believe that these patents are relevant to the subject matter presently claimed herein, the Examiners attention is drawn to copending applications derived from the above USSN 09/485,625 application. These include: USSN 10/464,968; USSN 10/993,272; USSN 10/993,458; USSN 10/993,550; USSN 10/993,983; and USSN 10/993,984.

For all the reasons enumerated above, as well as the fact that the claimed subject matter is different, Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

For the foregoing reasons, Claims 19, 21 to 27, 29 to 48 are not believed to be *prima facie* obvious in view of the cited references. Applicants respectfully request the issuance of a Notice of Allowance.

Should the Examiner have any additional questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. If any additional fees or charges are required by this paper the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,

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432 F.3d 1368, *; 2005 U.S. App. LEXIS 28061, **;
77 U.S.P.Q.2D (BNA) 1321

NICHOLAS V. PERRICONE, M.D., Plaintiff-Appellant, v. MEDICIS PHARMACEUTICAL CORPORATION, Defendant-Cross Appellant.

05-1022, 05-1023

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

432 F.3d 1368; 2005 U.S. App. LEXIS 28061; 77 U.S.P.Q.2D (BNA) 1321

December 20, 2005, Decided

PRIOR HISTORY: [**1] Appealed from: United States District Court for the District of Connecticut. Judge Christopher F. Droney. *Perricone v. Medicis Pharm. Corp., 267 F. Supp. 2d 229, 2003 U.S. Dist. LEXIS 10230 (D. Conn., 2003)*

COUNSEL: Raphael V. Lupo, McDermott Will & Emery, of Washington, DC, argued for plaintiff-appellant. With him on the brief were Charles R. Work, Mark G. Davis and David A. Spenard. Of counsel were Mary C. Chapin and Evan Parke.

William J. McNichol, Jr., Reed Smith LLP, of Philadelphia, Pennsylvania, argued for defendant-cross appellant. With him on the brief were Tracy Zurzolo Frisch, Maryellen Feehery and Heather A. Ritch. Of counsel was Charles L. Becker.

JUDGES: Before RADER, BRYSON, and LINN, Circuit Judges. Opinion for the court filed by Circuit Judge RADER. Concurring in part and dissenting in part opinion filed by Circuit Judge BRYSON.

OPINION BY: RADER

OPINION: [*1371] RADER, Circuit Judge.

On summary judgment, the United States District Court for the District of Connecticut, No. 3:99-CV-01820, determined that all of the asserted claims of Dr. Nicholas V. Perricone's *U.S. Patent Nos. 5,409,693* (the *'693 patent*) and *5,574,063* (the *'063 patent*) are invalid and, as to the *'693 patent*, not infringed. *Perricone v. Medicis Pharm. Corp., 267 F. Supp. 2d 229 (D. Conn. 2003).* [**2] Dr. Perricone seeks reversal of those judgments while Medicis Pharmaceutical Corporation cross-appeals the district court's refusal to declare the case exceptional under *35 U.S.C. § 285* and to award Medicis its attorney fees. Because the district court erred in its anticipation analysis with respect to claims 1-4 and 7 of the *'693 patent*, this court reverses and remands the judgments on those claims of the *'693 patent*. This court otherwise affirms the trial court's decisions of anticipation based on inherency for the remaining claims of the *'693* and *'063 patents* and its double-patenting analysis with respect to claims 9, 11-13, 16, 18, and 19 of the *'063 patent*. Finally, this court affirms the district court's denial of Medicis' motion under *§ 285*.

I.

Dr. Perricone's patents claim methods of treating or preventing sunburns (the *'693 patent*) and methods of treating skin damage or disorders (the *'063 patent*). The *'693 patent* issued in 1995, tracing priority back to a filing in 1989. The *'063 patent* issued in 1996, with priority back to the application that resulted in the *'693 patent*. The information added in that continuation-in-part application does not affect [**3] this case. Thus, both patents disclose essentially the same subject matter: treatment or prevention of various forms of skin damage through the topical application of ascorbic acid (Vitamin C) in a fat soluble form. See *'693 patent*, col. 2, ll. 26-34; *'063 patent*, col. 2, ll. 30-36. Specifically, the patents disclose the topical application of ascorbyl fatty acid ester (e.g., ascorbyl palmitate, ascorbyl laurate, ascorbyl myristate, ascorbyl stearate) with a dermatologically acceptable carrier. See *'693 patent*, col. 2, ll. 26-34; *'063 patent*, col. 2, ll. 30-36. Because the carrier, as well as the ascorbyl fatty acid ester, is fat soluble, it can "effectively penetrate skin layers and deliver the active ascorbyl fatty acid ester to the lipid-rich layers of [*1372] the skin." *'693 patent*, col. 4, ll. 4-6; *'063 patent*, col. 4, ll. 10-12. Upon reaching the lipid-rich layers of skin, the ascorbyl fatty acid ester produces a number of beneficial effects ranging from the acceleration of collagen synthesis to the scavenging of oxygen-containing radicals caused by exposure to damaging ultraviolet radiation. See *'693 patent*, col. 5, ll. 30-35, col. 6, ll. 35-50; *'063 patent*, col. 6, ll. [**4] 3-15, col. 7, ll. 30-45.

In 1999, Dr. Perricone sued Medicis, alleging that Medicis infringed both the *'693* and *'063 patents* with its LUSTRAA (R) line of prescription skin depigmenters.

Perricone, 267 F. Supp. 2d at 232-33. LUSTRAA (R) is a cream that, with hydroquinone as its active ingredient, reduces the production of melanin, i.e., the pigment in skin. LUSTRAA (R) also includes, inter alia, ascorbyl palmitate. Before the district court, Dr. Perricone filed motions for summary judgment of validity and infringement, and Medicis filed a motion for partial summary judgment of invalidity of claims 9, 11-13, 16, 18, and 19 of the *'063 patent* on the basis of double patenting, and of claims 1-19 of the *'063 patent* and claims 1-4, 7-9, and 13 of the *'693 patent* on the basis of anticipation. *Id. at 233*. Medicis also filed motions for partial summary judgment of non-infringement, premised on the invalidity of Dr. Perricone's asserted claims, and for attorney fees under *35 U.S.C. § 285*. Aside from the rejected attorney fees request, the district court granted Medicis' motions and denied Dr. Perricone's. *Id. at 249*. [**5]

The district court's opinion and the parties' briefs before this court do not disclose the disposition of each claim of the *'693* and *'063 patents*. The district court's opinion appears to invalidate all of the asserted claims of both patents, yet grants summary judgment of non-infringement only for the *'693 patent*. See id. Dr. Perricone's opening brief suggests that the district court's non-infringement ruling applies to the asserted claims of both patents. Dr. Perricone's opening brief at 1. Nevertheless, this court need not determine the correct status of each claim. Rather, this court confines its rulings to reversal of a clearly identifiable subset of the *'693* claims and trusts the parties to resolve any uncertainty on remand.

II.

This court reviews a district court's grant of summary judgment without deference and a denial of summary judgment for an abuse of discretion, *Electromotive Div. of Gen. Motors Corp. v. Transp. Sys. Div. of Gen. Elec. Co., 417 F.3d 1203, 1209 (Fed. Cir. 2005)*, drawing all reasonable inferences in favor of the nonmovant. This court gives due weight to a patent's presumed validity under *35 U.S.C. § 282 (2000)*, [**6] requiring an accused infringer to prove invalidity by clear and convincing evidence. *Geneva Pharm., Inc. v. GlaxoSmith-Kline PLC, 349 F.3d 1373, 1377 (Fed. Cir. 2003)*. This court reviews double patenting without deference. *Georgia-Pacific Corp. v. U.S. Gypsum Co., 195 F.3d 1322, 1326 (Fed. Cir. 1999)*.

Double Patenting

The double patenting doctrine generally prevents a patentee from receiving two patents for the same invention. Thus, this doctrine polices the proper application of the patent term for each invention. The proscription against double patenting takes two forms: statutory and non-statutory. Statutory, or "same invention," double patenting is based on the language in *§ 101* of the Patent Act mandating [*1373] "a patent" for any new and useful invention. *35 U.S.C. § 101 (2000)*; *In re Goodman, 11 F.3d 1046, 1052 (Fed. Cir. 1993)* ("If the claimed inventions are identical in scope, the proper rejection is under *35 U.S.C. § 101* because an inventor is entitled to a single patent for an invention.") (citations omitted). Non-statutory, or "obviousness-type," double patenting is a judicially [**7] created doctrine adopted to prevent claims in separate applications or patents that do not recite the "same" invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection. *Gerber Garment Tech., Inc. v. Lectra Sys., Inc., 916 F.2d 683, 686 (Fed. Cir. 1990)* (citing *In re Thorington, 57 C.C.P.A. 759, 418 F.2d 528, 534 (CCPA 1969)*). This case involves double patenting in this latter category.

Claim 1 of the *'693 patent* recites:

> 1. A method for treating skin sunburn comprising topically applying to the skin sunburn a fatty acid ester of ascorbic acid effective to solubilize in the lipid-richlayers of the skin an amount effective to scavenge therefrom free radicals present as a result of transfer of energy to the skin from the ultraviolet radiation which produced said sunburn.

'693 patent, col. 7. Meanwhile, claim 9 of the *'063 patent* recites:

> 9. A method for the treatment of skin damaged or aged by oxygen-containing free radicals or oxidative generation of biologically active metabolites which comprises topically applying to affected skin areas a composition [**8] containing an effective amount of an ascorbyl fatty acid ester in a dermatologically acceptable, [*1374] fat-penetrating carrier such that the ester is percutaneously delivered to lipid-rich layers of the skin.

'063 patent, cols. 8-9. The district court found claim 9 of the *'063 patent* invalid under the non-statutory double patenting doctrine in view of claim 1 of the *'693 patent*. In reaching that conclusion, the district court first identified differences between the two claims:

> (1) claim 9 of the *'063 patent* teaches a method for treatment of certain skin disorders, while claim 1 of the *'693 patent* teaches a method for treatment of sunburn; (2) claim 9 of the *'063 patent* recites

> the use of "an effective amount of an ascorbyl fatty acid ester . . . ," while claim 1 of the *'693 patent* teaches applying an ascorbyl fatty acid ester "effective to solubilize in the lipid-rich layers of the skin an amount effective to scavenge free radicals present as a result of the transfer of energy to the skin from the ultraviolet radiation which produced the sunburn"; and (3) claim 9 of the *'063 patent* recites the use of "a dermatologically acceptable, fat-penetrating carrier such that the [**9] ester is percutaneously delivered to lipid-rich layers of the skin," while the *'693 patent* does not explicitly recite the use of a carrier.

Perricone, 267 F. Supp. 2d at 240. The district court analyzed those distinctions. In the first place, the district court noted that "sunburn is a species of the genus of skin disorders" covered by the *'063 patent*. Id. Next, consulting the specifications of both patents, the district court concluded that the claimed effective amount in the *'063 patent* falls within the ranges of effective amounts in the *'693 patent*. Finally, the district court construed the "effective to solubilize" language in claim 1 of the *'693 patent* to mean the same thing as the language in claim 9 of the *'063 patent* requiring "a dermatologically acceptable, fat-penetrating carrier such that the ester is percutaneously delivered to lipid-rich layers of the skin." Accordingly, the district court found claim 9 of the *'063 patent* invalid for obviousness-type double patenting in view of claim 1 of the *'693 patent*.

Claims 11-13 of the *'063 patent* all depend from independent claim 9. Thus, the district court's analysis of claim 9 applies equally to claims [**10] 11-13. Claim 11 includes an additional limitation specifying a particular range of concentration of the ester. Because that range substantially overlaps the range in claim 5 of the *'693 patent* (dependent on claim 1 of the *'693 patent*), the district court determined that claim 11 of the *'063 patent* is also obvious in view of claim 5 of the *'693 patent*. *Id. at 242*. For claims 12 and 13 of the *'063 patent*, the district court determined that those claims added the same limitations to independent claim 9 as claims 3 and 4 added to claim 1 of the *'693 patent*. Thus, the district court determined that dependent claims 11-13 fall with claim 9 of the *'063 patent* for the above reasons. *Id. at 241*.

Independent claim 16 of the *'063 patent* includes limitations analogous to those in independent claim 9. Accordingly, the district court applied the same reasoning for its double patenting determination of claim 16. *Id. at 241-42*. The district court paid special attention to the additional recitation in claim 16 of specific "tocotrienols," but determined that those tocotrienols are not patentably distinct from the Vitamin E of claim 7 of the *'693 patent*. [**11] Finally, the district court determined that claims 18 and 19 of the *'063 patent*, which both depend from claim 16 of that patent, are not patentably distinct from claims 4 and 7.

This court first examines the contention that the claims of the *'063 patent* contain "material differences" from those in the *'693 patent*. This "material differences" argument does not show that the district court erred in its double patenting analysis. Rather, the district court's analysis specifically addresses differences between the claims of the *'693* and *'063 patents*. For instance, the district court discussed the difference between the recitation in the *'063 patent*'s claim 9 of "a dermatologically acceptable fat-penetrating carrier" and claim 1's recitation of no carrier at all. Thus, the district court cogently reasoned that, based on the specification, the "effective to solubilize" language in claim 1 of the *'693 patent* means the same thing as the "carrier" language in claim 9. Thus, the difference disappears.

Likewise, the district court properly resolved the apparent difference between treatment of various types of skin damage in claims 9 and 16 of the *'063 patent* and treatment of sunburn in claim [**12] 1. Sunburn is a species of skin damage. As such, this court perceives no error in the district court's determination that the earlier species renders the later genus claims invalid under nonstatutory double patenting. See *Eli Lilly & Co. v. Barr Labs., Inc. 251 F.3d 955, 971 (Fed. Cir. 2001)* ("[This court's] case law firmly establishes that a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim.") (citations omitted).

Finally, the district court did not misconstrue the genus-species relationship between claim 16 of the *'063 patent* and claim 7 of the *'693 patent*. The district court interpreted the language of claim 16 reciting various tocotrienols, and concluded that it "refers to certain forms of tocopherols, or Vitamin E." *Perricone, 267 F. Supp. 2d at 238*. [*1375] Thus, the district court did not improperly conclude that a species was obvious in light of an earlier claim to a genus but correctly concluded that there was no patentable distinction between the language of claim 16 of the *'063 patent* and claim 7 of the *'693 patent*. This court finds no error in that analysis.

The district court [**13] also considered and correctly rejected the suggestion that procedures of the United States Patent and Trademark Office (PTO) militate against double patenting. Specifically, if Dr. Perricone had presented all the claims of the *'693* and *'063*

patents to the PTO in a single application, the PTO might have made a restriction requirement. In other words, the PTO might have separated the claimed subject matter into different classifications and different inventions. If the PTO had entered a restriction requirement under that hypothetical situation, *35 U.S.C. § 121* would have barred a double patenting rejection. Yes, and if the court had a brother, he might like buttermilk. In other words, this tortured hypothetical does not correspond to the record in this case. The various claims were not filed together nor restricted by the PTO. Thus, in simple terms, *35 U.S.C. § 121* does not rescue Dr. Perricone's voluntarily filed continuation-in-part application.

Finally, and contrary to the suggestion by the district court, the Patent Act and PTO rules support the filing of a terminal disclaimer even after issuance of the second patent. See *35 U.S.C. § 253* [**14] *(2000)* ("Any patentee. . . may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted . . . ."); *37 CFR § 1.321(a)* (incorporating the language of *§ 253*). The district court's focus on *In re Goodman, 11 F.3d 1046, 1052 (Fed. Cir. 1993)* (explaining that a terminal disclaimer can overcome a double patenting "rejection") seems to have led to its conclusion that a terminal disclaimer cannot be filed for an issued patent to overcome invalidity based on double patenting. The commentary from *In re Goodman* arose in the context of ex parte prosecution, a setting not applicable to this case. An applicant must always overcome every rejection to gain issuance of a patent. Accordingly, the pre-issuance timing requirement of a terminal disclaimer to overcome a double patenting rejection does not dictate a prohibition on post-issuance terminal disclaimers. A terminal disclaimer can indeed supplant a finding of invalidity for double patenting. See *Applied Materials, Inv. v. Semiconductor Materials Am., Inc., 98 F.3d 1563, 1577 (Fed. Cir. 1996)* ("For obviousness-type double patenting, [**15] [the improper extension of the statutory term] problem can sometimes be avoided for co-owned patents. . . through the use of a terminal disclaimer."). This record, however, does not include any evidence of a disclaimer even though the district court invalidated the claims over two years ago. Thus, while Dr. Perricone might still file a terminal disclaimer to overcome prospectively the double patenting basis for invalidity, this court makes no determination about the retrospective effect of such a terminal disclaimer.

Anticipation

A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1565 (Fed. Cir. 1992)*. Thus, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency. See [*1376] *In re Cruciferous Sprout Litig., 301 F.3d 1343, 1349 (Fed. Cir. 2002)*. "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates." Id. (quoting *MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed. Cir. 1999)*. [**16] Moreover, "inherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art." Id.; see also *Schering Corp. v. Geneva Pharms., 339 F.3d 1373, 1377 (Fed. Cir. 2003)* (rejecting the contention that inherent anticipation requires recognition in the prior art) (citing *In re Cruciferous Sprout Litig., 301 F.3d at 1351*; *MEHL/Biophile, 192 F.3d at 1366*).

The district court determined that *U.S. Patent No. 4,981,845* (Pereira) anticipates claims 1-4, 7-9, and 13 of the *'693 patent*, and claims 1-19 of the *'063 patent*. *Perricone, 267 F. Supp. at 243*. Pereira teaches a cosmetic composition for topical application and discloses various ingredients in that composition, including skin benefit ingredients, emollients, emulsifiers, and thickeners. See Pereira, cols. 1-2. In addition to listing examples, Pereira discloses eight distinct example compositions with specific concentrations of ingredients. Id. at cols. 8-12. Pereira identifies the disclosed compositions only briefly, identifying [**17] them as "suitable for topical application to the skin or hair." Pereira, col. 1, ll. 6-8. The district court concluded that Pereira's disclosed use anticipates Dr. Perricone's claims because Pereira's disclosed compositions include all the various ingredients in the concentrations claimed by Dr. Perricone. Thus, according to the district court, the topical application of Pereira's compositions would necessarily yield Dr. Perricone's claimed skin benefits. On appeal, Dr. Perricone argues that: (1) Pereira's disclosed skin benefit ingredients include ascorbyl palmitate among many others, and so Pereira's disclosure does not anticipate the specific claimed use of ascorbyl palmitate; (2) Pereira's disclosed range of concentration of its skin benefit ingredient only partially overlaps with Dr. Perricone's claimed range; and (3) Pereira does not disclose any benefit directed to skin sunburn, or any of the other specific skin disorders, as claimed by Dr. Perricone.

With respect to its skin benefit ingredient, Pereira discloses "from 0.01 to 20% by weight of a skin benefit ingredient chosen from: . . . Ascorbyl palmitate and Tocopherol [i.e., Vitamin E] . . . ." Pereira, col. 1, ll. 55-68. In [**18] addition to those two identified ingredients, Pereira lists an additional twelve ingredients. See id. In total, Pereira teaches a total of fourteen skin benefit ingredients. This court rejects the notion that one of these ingredients cannot anticipate because it appears without

special emphasis in a longer list. To the contrary, the disclosure is prior art to the extent of its enabling disclosure. See *Hewlett-Packard Co. v. Mustek Sys., Inc., 340 F.3d 1314, 1324 n.6 (Fed. Cir. 2003)* ("The anticipation analysis asks solely whether the prior art reference discloses and enables the claimed invention, and not how the prior art characterizes that disclosure or whether alternatives are also disclosed.") (citing *Celeritas Techs. v. Rockwell Int'l Corp., 150 F.3d 1354, 1361 (Fed. Cir. 1998)*).

In re Baird, 16 F.3d 380, 383 (Fed. Cir. 1994), is not inconsistent with this anticipation analysis. In the first place, *In re Baird* involved obviousness, not anticipation. Baird observes that "disclosure of [*1377] millions of compounds does not render obvious a claim to three compounds." *16 F.3d at 383* (emphasis added). [**19] Baird's reasoning, relevant to obviousness, does not apply to Pereira's disclosure of a handful of different compositions, the use of one of which anticipates Dr. Perricone's claims.

While other opinions state that disclosure of a broad genus does not necessarily specifically disclose a species within that genus, see, e.g., *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1262 (Fed. Cir. 1989)*, this axiomatic proposition also does not rescue Dr. Perricone's claims. In this case, the prior art does not merely disclose a genus of skin benefit ingredients without disclosing the particular claimed ingredient. Rather Pereira specifically discloses ascorbyl palmitate. That specific disclosure, even in a list, makes this case different from cases involving disclosure of a broad genus without reference to the potentially anticipating species. Thus, these cases do not alter the district court's correct anticipation reasoning.

Pereira's disclosed range of concentration also does not exactly correspond to Dr. Perricone's claimed range. Pereira's disclosure nonetheless discloses and anticipates Dr. Perricone's particular claimed "effective amount" [**20] ranges. Dr. Perricone's claims recite a number of different ranges associated with the fatty acid ester. Those claimed ranges vary in breadth from an "effective" amount in claim 1 to particular specific ranges in other claims (e.g., "up to 10% by weight," *'063 patent*, claim 2; "from about 0.025% to about 5% by weight," *'063 patent*, claim 3; "from about 0.025% to about 10% by weight," *'063 patent*, claim 22). Pereira discloses a range of concentration "from 0.01 to 20% by weight." Pereira, col. 1, ll. 55-68. As the district court correctly noted, Pereira's range entirely encompasses, and does not significantly deviate from, Dr. Perricone's claimed ranges. Thus, this court sustains the district court's reading of Pereira's effective amount disclosure. See *Atlas Powder Co. v. IRECO Inc., 190 F.3d 1342, 1346 (Fed. Cir. 1999)* ("When a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls within each of the ranges anticipates the claim.") (citing *Titanium Metals Corp. v. Banner, 778 F.2d 775, 781 (Fed. Cir. 1985)*).

With respect to the particular claimed skin benefits, the district court [**21] reasoned that "Pereira will inherently function in [the claimed beneficial manner]when topically applied to the skin." *Perricone, 267 F. Supp. 2d at 248*. Thus, the district court ultimately based its anticipation analysis on inherency. "In general, a limitation or the entire invention is inherent and in the public domain if it is the 'natural result flowing from' the explicit disclosure of the prior art." *Schering, 339 F.3d at 1379* (citing *Eli Lilly &Co. v. Barr Labs., Inc., 251 F.3d 955, 970 (Fed. Cir. 2001)*; *In re Kratz, 592 F.2d 1169, 1174 (CCPA 1979)*). In some cases, the inherent property corresponds to a claimed new benefit or characteristic of an invention otherwise in the prior art. In those cases, the new realization alone does not render the old invention patentable. See *Atlas Powder, 190 F.3d at 1347* ("The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's function, does not render the old composition patentably new to the discoverer."); *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, [*1378] *Inc., 246 F.3d 1368, 1376 (Fed. Cir. 2001)* [**22] (explaining that newly discovered results of known processes are not patentable because those results are inherent in the known processes). Thus, when considering a prior art method, the anticipation doctrine examines the natural and inherent results in that method without regard to the full recognition of those benefits or characteristics within the art field at the time of the prior art disclosure.

Dr. Perricone's five asserted independent claims recite:

> [Claim 1, *'693 patent*] A method for treating skin sunburn comprising topically applying to the skin sunburn a fatty acid ester of ascorbic acid . . . .
>
> [Claim 8, *'693 patent*] A method for preventing sunburn damage to exposed skin surfaces, comprising topically applying to said skin surfaces . . . .
>
> [Claim 1, *'063 patent*] A method for the treatment of skin disorders which arise because of depleted or inhibited collagen synthesis which comprises topically applying to affected skin areas . . . .
>
> [Claim 9, *'063 patent*] A method for the treatment of skin damaged or aged by . . . which comprises topically applying to

> affected skin areas a composition containing . . . .
>
> [Claim 16, *'063 patent*] A method for the treatment [**23] of damaged or aging skin and epithelial tissue disorders. . . said treatment comprising topically applying to affected tissue areas the combination of . . . .

Thus, Dr. Perricone's independent claims recite particular skin benefits together with methods of achieving those benefits (i.e., topically applying a particular compound). * If Pereira discloses the very same methods, then the particular benefits must naturally flow from those methods even if not recognized as benefits at the time of Pereira's disclosure. Thus, Pereira anticipates if its disclosure of "topical application" satisfies the application step in Dr. Perricone's various asserted claims.

> * This court notes that while the various claimed beneficial uses appear to be recited in the preambles of Dr. Perricone's claims, the district court construed those claims as being limited by their preambles, see *Perricone, 267 F. Supp. 2d at 237* (determining the scope of various preamble terms), and neither party seems to have challenged that construction. This court agrees that the district court's construction was correct.

Claim 1 of the *'693 patent*, from which claims 2-4 and 7 ultimately [**24] depend, specifically recites application of the fatty acid ester to "skin sunburn." This claim term raises a different problem. The issue is not, as the dissent and district court imply, whether Pereira's lotion if applied to skin sunburn would inherently treat that damage, but whether Pereira discloses the application of its composition to skin sunburn. It does not. This court explained in Catalina Marketing International, Inc. v. Cool Savings.com, Inc. that a patent to an apparatus does not necessarily prevent a subsequent inventor from obtaining a patent on a new method of using the apparatus. *289 F.3d 801, 809 (Fed. Cir. 2002)*. New uses of old products or processes are indeed patentable subject matter. See *35 U.S.C. § 101 (2000)* (identifying as patentable "any new and useful improvements" of a process, machine, manufacture, etc.); *In re King, 801 F.2d 1324, 1326 (Fed. Cir. 1986)* (principles of inherency do not prohibit a process patent for a new use of an old structure). That principle governs in this case as well.

Claim 1 of the *'693 patent* recites a new use of the composition disclosed by Pereira, [*1379] i.e., the [**25] treatment of skin sunburn. The district court's inherent anticipation analysis for this claim contains a flaw. The disclosed use of Pereira's lotion, i.e., topical application, does not suggest application of Pereira's lotion to skin sunburn. In other words, the district court's inherency analysis goes astray because it assumes what Pereira neither disclosed nor rendered inherent. Because Pereira does not disclose topical application to skin sunburn, this court reverses the district court's holding that Pereira anticipates claims 1-4 and 7 of the *'693 patent*.

Like the district court, the dissent seems to ignore, or at least dismiss as "not substantial[]," the distinction between Dr. Perricone's claimed method and Pereira's disclosed method. Thus, the dissent characterizes both methods the same way: "Pereira describes not only the same product that is claimed in the sunburn patent, but also the same method of using it, i.e., topically applying it to the skin in an amount necessary to have beneficial effects on the skin." Unfortunately, the dissent can make that statement only by dismissing the explicit language of Dr. Perricone's claimed method: "applying to the skin sunburn. [**26] " *'693 patent*, claim 1. Skin sunburn is not analogous to skin surfaces generally. Thus, there is an important distinction between topical application to skin for the purpose of avoiding sunburn, and the much narrower topical application to skin sunburn. That distinction highlights the flaw in the dissent's knee brace hypothetical, which suggests that a particular prevention method necessarily anticipates a treatment method. To use a more apt analogy, the disclosure that a sunburn can be prevented by wearing a hat clearly does not anticipate a claim to the discovery that one can treat an existing sunburn by putting on a hat. The dissent attempts to bolster its analogy by comparing the mechanism underlying its knee brace analogy to Dr. Perricone's invention. With that comparison, the dissent drifts even farther from the facts of this case. The alleged anticipating reference here is Pereira, not Dr. Perricone's own teachings. Pereira is silent about any sunburn prevention or treatment benefits, not to mention the mechanisms underlying such uses. If Pereira did teach sunburn prevention, as well as the mechanism behind that prevention, those teachings might suggest that Dr. Perricone's sunburn [**27] treatment claims would have been obvious. However, those unrealized possibilities do not alter the analysis in this case where Pereira does not disclose topical application to skin sunburn.

Unlike claim 1, claim 8 of the *'693 patent*, from which claims 9 and 13 ultimately depend, merely requires application of the composition to exposed skin surfaces. Because all skin surfaces are susceptible to sunburn damage, and because one can only realistically apply a composition to a skin surface when that surface is exposed, Pereira's "topical application" encompasses the application step of claim 8. Thus, the district court

correctly determined that Pereira's disclosure of the topical application of the same composition necessarily anticipates claims 8, 9, and 13 of the *'693 patent*.

Claim 1 of the *'063 patent*, from which claims 2-8 of that patent ultimately depend, recites application to "affected skin areas." That claim further recites that those skin areas suffer from "depleted or inhibited collagen synthesis." *'063 patent*, claim 1. The specification of the *'063 patent*, meanwhile, explains that such damage results from, inter alia, "the natural aging process." *'063 patent*, col. 1, ll. [**28] 46-50. Because [*1380] all skin is a victim of that process, claim 1 of the *'063 patent* ultimately claims merely the topical application of the recited composition. Likewise, claim 9 of the *'063 patent*, from which claims 10-15 of that patent ultimately depend, recites application of the composition to "affected skin areas" where those areas are further identified as being "aged." As such, because all skin ages, the application step of claim 9 merely requires application of the composition to skin. Similarly, the "affected tissue areas" of claim 16 of the *'063 patent*, from which claims 17-25 ultimately depend, are identified in that claim as "aging skin." Thus, as with claims 1 and 9 of the *'063 patent*, claim 16 claims merely the topical application of the recited composition. Because Pereira discloses the very same composition and teaches its topical application, the district court correctly applied the inherency doctrine. Using the same composition claimed by Dr. Perricone in the same manner claimed by Dr. Perricone naturally results in the same claimed skin benefits.

In an effort to support the district court's invalidity ruling on other grounds, Medicis has directed this court's attention [**29] to a number of other references that Medicis argues anticipates Dr. Perricone's claims. This court declines to consider grounds for invalidity not relied on by, and not appealed from, the district court.

Infringement

Recognizing that invalidity is an affirmative defense to infringement, the district court granted Medicis' motion for summary judgment of non-infringement of the *'693 patent*. *Perricone, 267 F. Supp. 2d at 248-49*. The district court likewise denied Dr. Perricone's motion for summary judgment of infringement. Because it reverses the district court's grant of summary judgment on claims 1-4 and 7 of the *'693 patent*, this court also vacates the district court's summary judgment of non-infringement on those claims.

Attorney Fees

In the cross-appeal, Medicis challenges the districtcourt's denial of its motion for attorney fees under *§ 285*. Medicis asks this court either to remand on the exceptional case question or to "declare the case exceptional without further proceedings." Medicis' opening brief at 64. This court declines that invitation.

An award of attorney fees under *35 U.S.C. § 285* involves a two-part determination. [**30] First, a district court must determine whether the prevailing party has proven an exceptional case by clear and convincing evidence. *Forest Labs., Inc. v. Abbott Labs., 339 F.3d 1324, 1327 (Fed. Cir. 2003)* (citing *Ruiz v. A.B. Chance Co., 234 F.3d 654, 669 (Fed. Cir. 2000)*). This court reviews an exceptional case finding for clear error. *Id. at 1328*. Second, if the district court finds the case exceptional, it must then determine whether an award of attorney fees is appropriate. Id. This court reviews that determination for an abuse of discretion. Id. (citing *Cybor Corp. v. FAS Techs., 138 F.3d 1448, 1460 (Fed. Cir. 1998)* (en banc)). As this court explained in Frank's Casing Crew v. Weatherford International, trial judges enjoy discretion to award attorney fees for good reason. *389 F.3d 1370, 1379 (Fed. Cir. 2004)*. "After presiding over the preparation and trial of the case, the trial judge can best weigh the relevant considerations, such as the closeness of the case, the tactics of counsel, the flagrant or good faith character of the parties' conduct, and any other factors contributing to imposition [**31] [*1381] of punitive sanctions or to fair allocation of the burdens of litigation." Id. (citing *Modine Mfg. Co. v. Allen Group Inc., 917 F.2d 538, 543 (Fed. Cir. 1990)*; *S.C. Johnson & Son, Inc. v. Carter-Wallace, Inc., 781 F.2d 198, 201 (Fed. Cir. 1986)*). This case exhibits those considerations.

Medicis' arguments appear to focus on the timing and content of various expert reports proffered by Dr. Perricone, the propriety of various responses by Dr. Perricone to Medicis' requests for admissions, and demands made by Dr. Perricone during settlement negotiations. While the timing and content of some of those documents might be questionable, Medicis points to nothing establishing that the district court committed clear error regarding whether this case is exceptional. Moreover, even if this court determined that this case should have been declared exceptional, the district court's failure to award attorney fees would not rise to an abuse of discretion given that court's familiarity with the various relevant details of Dr. Perricone's conduct in this case.

CONCLUSION

This court affirms the district court's summary judgment of invalidity of claims 1-19 of [**32] the *'063 patent* and claims 8, 9, and 13 of the *'693 patent*. However, because the district erred in its anticipation analysis of claims 1-4 and 7 of the *'693 patent*, this court reverses the district court's summary judgment of invalidity as to those claims. Moreover, this court vacates the district court's summary judgment of non-infringement of claims

1-4 and 7 of the *'693 patent*, but affirms that summary judgment as to the remaining claims in that patent. Finally, this court affirms the district court's denials of Medicis' motion for attorney fees under *35 U.S.C. § 285*. This court remands for further proceedings.

COSTS

Each party shall bear its own costs.

AFFIRMED-IN-PART, REVERSED-IN-PART, VACATED-IN-PART and REMANDED

CONCUR BY: BRYSON (In Part)

DISSENT BY: BRYSON (In Part)

DISSENT: BRYSON, Circuit Judge, concurring in part and dissenting in part.

I concur in most aspects of the court's opinion, including the portions upholding the district court's ruling that claims 1-19 of the "skin disorder" patent, *U.S. Patent No. 5,574,063*, and claims 8, 9, and 13 of the "sunburn" patent, *U.S. Patent No. 5,409,693*, are anticipated by *U.S. Patent No. 4,981,845* ("the Pereira [**33] patent"). I dissent, however, from the portion of the judgment holding that the Pereira patent does not anticipate claims 1-4 and 7 of the sunburn patent. In my view, the differences between the claims that the court invalidates and those that it holds not to be invalid do not justify a difference in outcome. The written description of the sunburn patent is identical to the pertinent portions of the written description of the skin disorder patent in all material respects. The only significant difference between the two patents for present purposes is that the sunburn patent claims methods for treating and preventing sunburn comprising the topical application of the composition described in the specification, while the skin disorder patent claims a method for treating skin disorders comprising the topical application of the same composition. Moreover, the only difference between the claims of the sunburn patent that this court invalidates and those [*1382] that it upholds is that the former recite methods for preventing sunburn while the latter recite methods for treating sunburn. The differences between the sunburn and the skin disorder patents, and among the claims of the sunburn patent, [**34] simply highlight inherent features of the compositions that are disclosed both in the common written description of the two patents in suit and in the Pereira patent. Under our precedents, those differences do not suffice to avoid anticipation.

Claim 1 of the sunburn patent recites:

> A method for treating skin sunburn comprising topically applying to the skin sunburn a fatty acid ester of ascorbic acid effective to solubilize in the lipid-rich layers of the skin an amount effective to scavenge therefrom free radicals present as a result of transfer of energy to the skin from the ultraviolet radiation which produced said sunburn.

Dependent claims 2-4 and 7 recite a method for treating skin sunburn in which the fatty acid ester of ascorbic acid is topically applied to the skin in the form of a composition including a dermatologically acceptable carrier (claim 2), in which the fatty acid ester of ascorbic acid is selected from a group including ascorbyl palmitate (claim 3), in which the fatty acid ester of ascorbic acid is ascorbyl palmitate (claim 4), and in which the composition includes Vitamin E (claim 7). Independent claim 8 and dependent claims 9 and 13 are similar to claims [**35] 1, 2, and 7, except that they recite a method for preventing sunburn damage to exposed skin.

In explaining the effectiveness of the claimed method, the sunburn patent states:

> The effectiveness of the ascorbyl fatty acid esters in the treatment of . . . radiation-induced skin damage . . . can be postulated as resulting from the antioxidant properties of ascorbic acid per se, which properties are retained to a high degree in the ascorbyl fatty acid ester form, together with the fact that the ascorbyl fatty acid ester form is capable of being delivered in an effective manner.

Sunburn patent, col. 6, ll. 35-43. The patent further explains that "when solubilized in the lipid-rich layers of the skin, the fatty acid ester form of ascorbic acid is capable of scavenging free oxygen-containing radicals, neutralizing other reactive oxidants released extracellularly and intracellularly, and either interfering with or minimizing oxidative generation of metabolites . . . ." Id. col. 6, ll. 43-47. The patent describes the invention as one

> which involves the topical application of fat-soluble fatty acid esters of ascorbic acid . . . . By virtue of the fat-solubility of [**36] these fatty acid esters and the further enhancement of this solubility via admixture with fat-penetrating carriers, the active ascorbic acid can be effectively percutaneously delivered to lipid layers so as to bring about these effects and actions . . . .

Id. col. 6, ll. 50-63.

The Pereira patent discloses a composition containing each of the components recited in the sunburn patent, and in amounts falling within the same range. In addition, the Pereira patent discloses that the emulsion of the invention comprises "a selected skin benefit ingredient, a special emulsifier and an emollient oil," which is effective for delivering the skin benefit agent "to subcutaneous regions of the skin." Pereira patent, col. 1, ll. 14-15; id. col. 2, ll. 13-14. Among the skin benefit ingredients listed in the Pereira patent is [*1383] ascorbyl palmitate. Pereira further discloses a number of substances for use as the emollient ingredient, including lethicin. Id. col. 4, ll. 67-68.

The evidence before the district court established that the Pereira patent discloses topical application of the same substance that is claimed in the sunburn patent, with the same results. Thus, the evidence [**37] showed that certain of the skin benefit ingredients of Pereira, including ascorbyl palmitate, operate to benefit the skin by scavenging free radicals. In addition, the evidence showed that lecithin is a dermatologically acceptable carrier that is able to "solubilize the lipid-rich layers of the skin," as required by the sunburn patent. And the concentration levels of the skin benefit ingredients of Pereira encompass the levels that the sunburn patent asserts are effective in treating and preventing sunburn.

To be sure, Pereira does not expressly refer to the use of the disclosed composition to treat or prevent sunburn. As the district court noted, however, those benefits are inherent in the topical application of the composition claimed in Pereira. The fact that Pereira does not assert that the emulsion is effective in preventing or treating sunburned skin does not avoid anticipation of the sunburn patent, as long as those benefits are the natural result of the normal use of the Pereira emulsion. See *MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1366 (Fed. Cir. 1999)* (prior art article anticipates because it describes a process that necessarily performs [**38] the claimed process; "where . . . the result is a necessary consequence of what was deliberately intended, it is of no consequence that the article's authors did not appreciate the results"); *Atlas Powder Co. v. Ireco, 190 F.3d 1342, 1347 (Fed. Cir. 1999)* ("Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates."); *In re King, 801 F.2d 1324, 1326 (Fed. Cir. 1986)*, quoting *In re Ackenbach, 18 C.C.P.A. 769, 45 F.2d 437, 439, 1931 Dec. Comm'r Pat. 84 (CCPA 1930)* ("if a previously patented device, in its normal and usual operation, will perform the function which an appellant claims in a subsequent application for process patent, then such application for process patent will be considered to have been anticipated by the former patented device"). Although Dr. Perricone may have discovered that among the skin benefits of the composition disclosed by Pereira are the prevention and treatment of sunburn, the discovery of a new property of the Pereira composition, when used in accordance with its normal application, is not a sufficient basis for avoiding anticipation. See *In* [**39] *re Cruciferous Sprout Litig., 301 F.3d 1343, 1350-51 (Fed. Cir. 2002)* ("Brassica has done nothing more than recognize properties inherent in certain prior art sprouts . . . . While Brassica may have recognized something quite interesting about those sprouts, it simply has not invented anything new."); *EMI Group, N. Am., Inc. v. Cypress Semiconductor Corp., 268 F.3d 1342, 1349 (Fed. Cir. 2001)* ("The discovery of a previously unappreciated property of a prior art composition . . . does not render the old composition patentably new to the discoverer."); *Atlas Powder, 190 F.3d at 1349* ("discovery of an inherent property of the prior art [does] not [constitute] the addition of a novel element" and therefore does not serve as patentable subject matter).

This is not a case in which the patentee is claiming a method that consists of a new way of using a previously known product in order to achieve a new result. The Supreme Court long ago explained that "if [*1384] an old device or process be put to a new use which is not analogous to the old one, and the adaptation of such process to the new use is of such a character as to require the [**40] exercise of inventive skill to produce it, such new use will not be denied the merit of patentability." *Ansonia Brass & Copper Co. v. Elec. Supply Co., 144 U.S. 11, 18, 12 S. Ct. 601, 36 L. Ed. 327, 1892 Dec. Comm'r Pat. 313 (1892)*. Importantly, however, the Court qualified that rule by adding that "the application of an old process or machine to a similar or analogous subject, with no change in the manner of application and no result substantially distinct in its nature, will not sustain a patent even if the new form of result had not before been contemplated." Id.; see also *Brown v. Piper, 91 U.S. 37, 41, 23 L. Ed. 200, 1876 Dec. Comm'r Pat. 464 (1875)* (prior art patent for a "corpse preserver" anticipated method for preserving fish and meats that used the same steps; Court held that the new method "was simply the application by the patentee of an old process to a new subject . . . . The thing was within the circle of what was well known before, and belonged to the public. No one could lawfully appropriate it to himself, and exclude others from using it in any usual way for any purpose to which it may be desired to apply it.").

The majority accurately describes that governing principle of law when it states: [**41] "If Pereira discloses the very same methods, then the particular benefits must naturally flow from those methods even if not

recognized as benefits at the time of Pereira's disclosure." That principle, however, leads me to a conclusion different from the one reached by the majority, at least as to the sunburn treatment claims. In my view, the method of using the composition recited in the sunburn patent is not substantially different from the "skin benefit" use described by Pereira. The prevention and treatment of sunburn therefore do not qualify as "new uses" of the composition so as to avoid anticipation. See *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 809-10 (Fed. Cir. 2002)* (stating, for illustration, that a claimed use of shoe polish to repel water on shoes does not constitute a "new use" of the prior art polish, although a claimed use of the shoe polish to grow hair would so qualify).

Pereira describes not only the same product that is claimed in the sunburn patent, but also the same method of using it, i.e., topically applying it to the skin in an amount necessary to have beneficial effects on the skin. Dr. Perricone's contribution is [**42] simply to recognize that among those skin benefits is the prevention and treatment of sunburn. That identification of a new subset of a previously known property is not entitled to patent protection.

While the majority applies that principle to the sunburn prevention and skin disorder claims, it does not apply the same principle to the sunburn treatment claims, even though those claims recite the same composition and process as are disclosed in Pereira and recited in Dr. Perricone's other claims. Yet, to use the majority's language, the treatment of sunburned skin is every bit as much a "particular benefit[] that must naturally flow from [Pereira's] methods" as the prevention of sunburn and the treatment of skin disorders. Under the majority's test, the sunburn treatment claims should therefore be anticipated by Pereira just as much as the sunburn prevention claims and the skin disorder treatment claims.

The majority distinguishes the prevention claims of the sunburn patent from the treatment claims of that patent by stating [*1385] that because "all skin surfaces are susceptible to sunburn damage, and because one can only realistically apply a composition to a skin surface when that [**43] surface is exposed, Pereira's 'topical application' encompasses the application step of claim 8" of the sunburn patent. But precisely the same reasoning applies to the sunburn treatment claims. The majority seems to attach significance to the notion that topical application of Pereira's emulsion always prevents sunburn, because all skin is subject to sunburn, but that it does not always treat sunburn, because not all skin is sunburned and in need of treatment. That distinction, however, does not stand up: the fact that the sunburn treatment function is pertinent to only a subset of users of the Pereira method (i.e., those already suffering from sunburn) does not mean that Pereira does not anticipate the treatment claims.

Topical application of the Pereira emulsion results in scavenging oxygen-containing free radicals and neutralizing reactive oxidants, whether the skin is sunburned or not. Thus, the effect that underlies both the prevention and treatmentof sunburn is present in all cases of topical application of the Pereira composition. For that reason, Pereira anticipates not only the skin disorder and sunburn prevention claims, but also the sunburn treatment claims, which are based [**44] on the same underlying chemical processes. To illustrate the point, if it were discovered that using a particular kind of knee brace that was long worn by athletes to provide stability and thus minimize the effect of ligament injuries would also facilitate the treatment of cartilage damage and protect against further cartilage damage, that subsequent discovery would not give rise to a patentable invention. Moreover, it surely would not be the case that the use of the brace to prevent cartilage damage would be anticipated, but the use of the brace to treat cartilage damage would not, on the ground that all knees are subject to cartilage damage, but only some knees already have it.

The majority illustrates its distinction between sunburn treatment and sunburn prevention with its own analogy, arguing that the prior use of a hat to prevent sunburn would not anticipate the use of a hat to treat sunburn. Yet this analogy is inapt because a hat prevents sunburn by a mechanism, i.e., shade, that does not treat sunburn. In contrast, the mechanism by which a knee brace minimizes the effects of ligament injury, i.e., enhanced stability, is the same mechanism that facilitates treatment of cartilage [**45] damage and also prevents further cartilage damage. The same is true here, where the same chemical process treats and prevents sunburned skin.

Furthermore, the majority's distinction between the sunburn prevention claims, which the majority invalidates, and the sunburn treatment claims, which the majority upholds, is inconsistent with its invalidation of all the asserted claims of the skin disorder patent. The majority distinguishes the sunburn treatment claims by focusing on the applicability of the skin damage patent to aging skin, and suggests that "all skin is a victim of [the natural aging process]." The skin damage patent, however, addresses "[a] wide variety of skin diseases and skin conditions in which the skin has undergone some form of accelerated aging." Skin damage patent, col. 1, ll. 26-28. Like sunburn, those diseases and conditions are not found in all persons. The majority's distinction appears to rest upon its assertion that "skin sunburn is not analogous to skin surfaces generally." However, there appears to be [*1386] no greater specificity in topical application to skin that is sunburned than there is in topi-

cal application to skin that is diseased or skin that has [**46] suffered from accelerated aging. Accordingly, I submit that the majority's distinction between the treatment claims and the prevention claims is not a satisfactory ground for decision in this case.

This court's decisions in *Rapoport v. Dement, 254 F.3d 1053 (Fed. Cir. 2001)*, and *MEHL/Biophile International Corp. v. Milgraum, 192 F.3d 1362 (Fed. Cir. 1999)*, are not at odds with the district court's conclusion in this case. Each of those cases involved a prior art method that was directed at an objective different from the objective of the claimed invention. In Rapoport, the prior art was a method for treating anxiety by administering a certain dosage of a particular drug three times a day, while the invention was a method for treating sleep apnea by administering a larger dosage of the same drug at the time of sleep. In MEHL/Biophile, the prior art was a method of using a laser to remove tattoos by aligning the laser over the pigmented skin, while the claimed invention was a method of using a laser to remove hair by aligning the laser over hair follicles. Although in each case practicing the prior art method might sometimes have the effect [**47] that was the objective of the claimed invention, the court held in each case that practicing the prior art method would not inherently have that effect. Thus, even if the prior art method for tattoo removal were used on skin having hair, it would not anticipate the claimed method in MEHL/Biophile because the prior art method did not dictate that the laser be aligned with hair follicles. And even if the prior art treatment of anxiety were used on patients suffering from sleep apnea, it would not anticipate the claimed method in Rapoport because the timing of drug administration and the dosages employed in the two treatments were different.

In this case, by contrast, topical application of the Pereira composition to normal skin inherently produces the same chemical processes that underlie the sunburn prevention claims, including scavenging free-oxygen-containing radicals and neutralizing other reactive oxidants. Topical application of the Pereira composition to sunburned skin inherently produces the same processes, which also underlie the sunburn treatmentclaims. Because the chemical processes that have the effect of treating and preventing sunburn are inherent consequences [**48] of the normal use of the Pereira composition, Pereira anticipates all the claims of the sunburn patent, just as it anticipates all the claims of the skin disorder patent.

In substance, the sunburn patent simply selects particular ingredients from among the small class of ingredients identified in Pereira and identifies specific benefits falling within the broader characterization of benefits identified in Pereira. To hold that the treatmentclaims of the sunburn patent are not anticipated by Pereira is to permit an inventor to secure patent rights to an existing invention merely upon identifying an inherent benefit of the prior art that had not previously been specifically identified, but that falls within a broader class of benefits already identified in the prior art. Because that result is contrary to the law of inherent anticipation as I understand it, I respectfully dissent from the portion of the court's judgment relating to the treatment claims of the sunburn patent.